



# BIODEFENCE:

## New Opportunities for Canadian Industry and Policy Leaders

Just days into the second four-year term of U.S. President George W. Bush, the Senate Republican Majority Leadership announced that U.S. biodefence funding would be one of the top ten priorities of the 109th Congress in 2005 and introduced new legislation designed to spark billions of dollars of new investment to secure America and its allies against the threat of terrorist attacks using bioweapons like anthrax, smallpox and plague.

In the 2005 fiscal year alone, the U.S. will spend an estimated US \$7.6 billion on biodefence measures. On 24 January 2005, Republican Senator Judd Gregg introduced the *BioPreparedness Act* of 2005 (*BioShield II*). Together with the *Project BioShield Act* of 2004 (*BioShield I*), which created an initial US \$5.6 billion fund for biodefence vaccines and therapeutic drugs, the proposed *BioShield II* bill, which enjoys bipartisan support, is expected to ensure continued U.S. funding and industry growth well into the future.

The *BioShield* program recognizes that no single country is equipped to secure its people and warfighters against the full range of bioterror agents. As President Bush said in 2003, “right now, America must go beyond our borders to find companies willing to make vaccines to combat biological weapons.”

Many of the world’s top pharmaceutical companies are non-US companies. The technological challenge of creating and making the new drugs far exceeds America’s existing laboratory and manufacturing base. Both the threat and the industrial capacity to respond to it are global. And unlike conventional, chemical or even nuclear weapons, the impact of a bioweapon has no perimeter, but, like SARS, spreads swiftly and unpredictably, its effects accelerated by cross-border commerce and travel. Only multilateral strategies will succeed.



CENTRE FOR EMERGENCY PREPAREDNESS & RESPONSE, HEALTH CANADA

With Canadian companies already supplying U.S. requirements in this new industry, the *BioShield* program opens new channels for collaboration within the Canada-U.S. defence partnership, and offers valuable new trade and investment opportunities for Canada’s defence and biopharmaceutical industries.

### **BioShield I and II**

#### Creating A New U.S. Defence Marketplace

Weeks after the 9-11 attacks in the U.S., a still-unknown perpetrator mailed weapons-grade anthrax to Congressional offices in Washington, D.C., and to media outlets on the U.S. East Coast. Five people died. The event exposed the inability of America’s public health system to adequately respond to and contain a terror-triggered epidemic, particularly one involving an agent as lethal as anthrax. As one expert, John’s Hopkin’s Dr. Tara O’Toole, testified to a Senate committee after the attacks: “We must understand that public health is now an essential aspect of national security.”

Since 2001, federally-funded civilian biodefence programs in the U.S. totaled nearly US \$14.5 billion, and with the passage of *BioShield*, annual expenditures, like the US\$7.6 billion anticipated in FY2005, are expected to be the trend.

Combining aspects of the defence, biotechnology, health care, pharmaceuti-

cal and even construction industries, America’s new biodefence industry will be open to non-U.S. companies.

U.S. Project *BioShield* Act of 2004 (*BioShield I*), which President Bush signed into law last July, created an initial biodefence “special reserve fund” of US\$5.6 billion to fund medical countermeasures, R&D, and stockpiles – and to accelerate the research, development, purchase, and availability of countermeasures to combat bioterrorism threats.

But *BioShield I*’s special reserve fund, simplified acquisition rules and guaranteed contracts for new anti-terror drugs were not sufficient alone to mobilize the major pharmaceutical companies. Viagra and other blockbuster “civilian” products are simply too profitable for private industry to justify rededicating investment and expensive resources to develop drugs for exotic or erstwhile eradicated diseases like ebola, plague and smallpox. This is particularly true when the drugs are intended for a finite purchase (for U.S. strategic stockpiles) for a single, rather demanding customer (the U.S. government) at restricted profit margins. Not to speak of America’s famous plaintiff lawyers!

The proposed *BioShield II* sweetens the pot with several incentives to entice pharmaceutical companies, including:

- tax credits for investment in new laboratories, manufacturing capacity and medical research related to the development of vaccines or countermeasures;
- measures to limit the litigation risks of new product development; and
- opportunities for extended patent terms on newly-developed bioterror medical countermeasures or the option for an extension of up to two years on any unrelated patent held by the company (potentially worth billions)

Experts predict Congress will pass some form of *BioShield II* before summer.

## Canada/U.S. Trade

### New Directions for an Old Partnership

America's civilian biodefence programs after 9-11 contemplate highly expedited development and production pipelines to deliver products on an entirely new scale to first-responders and communities across the United States.

There is a Canadian company offering technology and/or services in every segment of the new industry, including:

- medical countermeasures (vaccines and therapies);
- detection, diagnostic and decontamination technologies;
- information and communications technologies;
- laboratories and other infrastructure.

Here is a small sampling of the Canadian companies already participating in the U.S. biodefence market – and poised for leadership in this new phase of the Canada-U.S. defence industrial partnership.



ID Biomedical's Ste-Foy facilities.

**ID Biomedical**, a Vancouver-based vaccine maker, is well-positioned to supply new U.S. needs for biodefence products. "ID Biomedical is pursuing a series of biodefence initiatives highlighted by our plague injectable vaccine," says Anthony Holler, MD, Chief Executive Officer. "Additionally, we have been awarded three NIH grants allowing us to conduct some development work on intranasal plague and SARS vaccines. These projects add to our biodefence assets and are another positive step in building this business unit." The company's substantial



Response Biomedical's industry-leading RAMP anthrax test.

production capacity includes a state-of-the-art facility near Quebec City.

**Response Biomedical Corp.**, of Vancouver, develops and manufactures rapid on-site diagnostic tests for the detection of anthrax, smallpox, ricin and botulinum toxin. A recent independent study commissioned by the U.S. Department of Homeland Security named the company's RAMP rapid immunoassay-based anthrax field test the top performer in its category. The company envisions potential new applications of its technology for a number of the other bioterror agents targeted by *BioShield*.

**Smith Carter Architects and Engineers, Inc.**, has designed highly specialized, secure biocontainment facilities for several of America's top bioterror research labs, including the Centers for Disease Control and Prevention in Atlanta, Georgia, and the University of Texas Medical Branch in Galveston, Texas. The company has established a U.S. headquarters and is well-positioned to pursue new projects expected to flow from *BioShield II*.

The new biodefence industry will rely upon new information technologies able to quickly gather information about disease outbreaks, alert first responders, and coordinate public health authorities at every level of government.

In late November, the Public Health Agency of Canada unveiled the Global Public Health Information Network (GPHIN), a global disease outbreak surveillance system based on a software platform designed by **Nstein Technologies, Inc.**, of Montreal. The project was developed with the financial support of media mogul Ted Turner, and the Nuclear Threat Initiative, a U.S.-based non-proliferation group.

## Canada: Poised for Leadership

With its consistent investment in public health and recent experiences dealing with infectious disease outbreaks, Canada offers the U.S. (and the world) valuable public resources for addressing the risks of global bioterror. After all, the same response mechanisms that Canada deployed to mitigate the SARS pandemic in 2003 would be required to respond to an attack using anthrax spores.

"Canada offers substantial assets in the infectious disease field, ready to be marshaled to the cause of North



Mr. Duguid (left) joined Manitoba's Premier, Gary Doer, on a recent trade mission to Texas to discuss continent-wide industry and public sector biodefence partnerships.

American biodefence," said Terry Duguid, President and CEO of the Winnipeg-based **International Centres for Infectious Diseases**. "Our U.S. collaborators value what we have to offer." Mr. Duguid joined Manitoba Premier Gary Doer on a recent mission to Texas – the agenda included cooperative North American biodefence strategies and infrastructure development

And there is no doubt that proven strategies will be needed as the U.S. proceeds with its programs. As Dr. Donald Henderson, Director of the Johns Hopkins Center for Civilian Biodefence Strategies, told a Canadian audience in October 2003, "I don't think there are two or three cities in the U.S. that could have achieved as good a result as what Toronto achieved during SARS."

Fortunately, the *BioShield* program will equip U.S. agencies with the funds, liability limitations, and incentives necessary quickly to execute their new biodefence mandate. Canada and its growing biodefence sector are well-positioned to contribute solutions. **FL**



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